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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,783	06/01/2001	Jingye Liu	CCP-100	4651

7590 03/25/2003

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EXAMINER

FOLEY, SHANON A 11

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/807,783	LIU ET AL.
	Examiner	Art Unit
	Shanon Foley	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 31 December 2002.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-3,5-8,11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-3,6,7,11 and 12 is/are rejected.
- 7) Claim(s) 5 and 8 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
- 1.) Certified copies of the priority documents have been received.
- 2.) Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- 3.) Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ .                                   |

## **DETAILED ACTION**

In paper no. 10, applicant amended claims 1, 3, 5-8, cancelled claims 4, 9, 10, and added new claims 11 and 12. Claims 1-3, 5-8, 11 and 12 are under consideration. Upon reconsideration, new grounds of rejection are established.

### ***Claim Objections***

Claims 3, 6 and 7 are objected to because of the following informalities: the claims either recite, “both of them” or a “mixture of them” when referring to mannitol and sorbitol. The phrase “of any of the foregoing”, recited before the list of alkali metal salts, encompasses each component as well as any combination of the components listed. Therefore, “both of them” or a “mixture of them” is extraneous. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Funkhouser et al. (US 6,113,912 or 6,180,110 B1, in the alternative).

The claim is drawn to formulation comprising a live, attenuated HAV and a stabilizer.

Funkhouser et al. anticipate a formulation comprising a live, attenuated HAV and a stabilizer, see column 17, lines 10-43 of US 6,113,912 or column 15, line 64 to column 16, line 29 of US 6,180,110 B1, in the alternative.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 6, 7, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chiba-ken et al. (JP 1279843 abstract provided with IDS in paper no. 5).

Applicant argues that there is no motivation present in the reference to add live HAV to the composition to the formulation of Chiba-ken et al. Applicant points out that the reference is more than 10 years old and discusses the dissatisfactory results of storage upon live HAV. Applicant hypothesizes the lack of motivation or failed attempts to incorporate an attenuated HAV into the formulation of Chiba-ken et al., but offers no foundation for either hypothesis.

Applicant's arguments, as well as a careful review of the reference have been considered, but are found unpersuasive. The claimed composition of claims 1 and 2 comprise two components: a live, attenuated enterovirus, HAV, and a stabilizer. The formulation of Chiba-ken et al. comprise a stabilized HAV, a gelatinizing agent, an amino acid, and sugars. These various classes of components are the same as those described as essential ingredients for the stabilizer recited in claims 3 and 7, i.e. gelatin, sugar and at least one amino acid. Although Chiba-ken et al. do not specifically teach trehalose, this is sugar conventionally used in vaccine formulations that could be used with a more than reasonable degree of success in the formulation of Chiba-ken et al. because the reference teaches that the formulation must comprise 15% of generic sugars.

Therefore, it is maintained that one of ordinary skill in the art at the time the invention was made would have been motivated to incorporate LAI, a live, attenuated hepatitis A virus, well known in the art, into the formulation of Chiba-ken et al. to expose the immune system to a replication-competent virus. Further, one of ordinary skill in the art at the time the invention was made would have had a reasonable expectation for producing the claimed invention because the same classes of ingredients are present in the instant claims and the formulation of Chiba-ken et al.

Claims 6 and 11 are drawn to a method of making an HAV formulation by obtaining an HAV stock suspension, adding a stabilizer and lyophilizing by cooling the formulation and drying by increasing the temperature.

Chiba-ken et al. teach obtaining an HAV virus, added with the stabilizing agent and freeze-dried. Although Chiba-ken et al. do not teach the exact temperatures used to perform lyophilization, -20°C is the conventional freezer temperature in laboratories and gradually increasing the composition to room temperature prevents the formation of condensation. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

***Allowable Subject Matter***

Claims 5 and 8 remain objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach or suggest a formulation comprising all of the ingredients at the recited concentrations.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Shanon Foley  
March 21, 2003



JAMES C. HOUSEL 3/23/03  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600